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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,652	11/25/2003	Glenn R. Gibson	8497-US	7110
74476	7590	10/31/2008		
Nestle HealthCare Nutrition 12 Vreeland Road, 2nd Floor, Box 697 Florham Park, NJ 07932			EXAMINER BARHAM, BETHANY P	
			ART UNIT	PAPER NUMBER
			1615	
			NOTIFICATION DATE	DELIVERY MODE
			10/31/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/721,652

Applicant(s)

GIBSON ET AL.

Examiner

BETHANY BARHAM

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-8,10,11,26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-8,10,11,26 and 27 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

Receipt is acknowledged of the Applicants' Response and Amended Claims filed on 07/07/08. Claims 1, 5-8, 10-11, and 26-27 are pending in this action. Claims 1, 5-8, 10-11 and 26-27 are rejected.

NEW OBJECTIONS/REJECTIONS

Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Currently, claim 1 requires fiber in the amount of 'about 25g', claim 5 requires 'about 20g or 15g', but claim 10 teaches that the composition contains 2.5 g which is nowhere near the about 25, 20 or 15g in the previous claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-8, 10-11 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 (from which 5-8, 10-11 and 26 depend) has been amended to claim "a daily dosage of said oligosaccharide blend is about 25 g", nowhere in the instant specification is a daily dosage of 25g disclosed. Paragraphs [0040-0041] of the publication of the instant specification to which Applicant claims support only discloses a range of about 1- about 20g, or about 20 or about 15, etc; there is no support for 25 g. This is a new matter rejection. Further, newly added claim 27 contains the transition phrase "consisting essentially of" and nowhere in the instant specification is there disclosed a composition which is only FOS and GOS, all of the instant examples contain other components such as glutamine or proteins, fats, etc (Examples 1-4). This is a new matter rejection.

Claims 1, 5-8, 10-11 and 26 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 2 g. (Example 2), 9.86g (Example 3), and 2.5g. (Example 4) of fiber from GOS and FOS, does not reasonably provide enablement for about 25, about 20 or about 15 (instant claim 1 and 5). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Based on the instant disclosure, it is the examiner's position that Applicants do not describe this invention in such a manner that would enable one of

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ordinary skill in the art to practice this invention at the higher claimed range of about 25g, about 20g or about 15g without undue burden. Further the instant (and original filed) claims are drawn to "a composition" (single), not an intended use/administration of a "daily dosage" that could require more than a single composition or multiples of the composition as intended use. This is a scope of enablement rejection.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

The breadth of claims: The instant claim 1 is directed to "a composition comprising an oligosaccharide blend that comprises fructo-oligoasaccharide (FOS) and galacto-oligoasaccharide (GOS), wherein (a) a daily dosage of said oligosaccharide blend is about 25 g; (b) each of said oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7; (c) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (d) the FOS and GOS are capable of synergistically promoting the growth of Lactobacilli, such that their combined prebiotic property is greater than the a sum of their individual prebiotic properties." It is the examiner's position that this claim is not supported by the instant specification, and that

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the scope supported by the specification includes 2 g. (Example 2), 9.86g (Example 3), and 2.5g. (Example 4) of fiber (FOS and GOS) in a single composition.

The nature of the invention: The instant invention is directed to a "a composition comprising an oligosaccharide blend that comprises fructo-oligoasaccharide (FOS) and galacto-oligoasaccharide (GOS), wherein (a) a daily dosage of said oligosaccharide blend is about 25 g; (b) each of said oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7; (c) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (d) the FOS and GOS are capable of synergistically promoting the growth of Lactobacilli, such that their combined prebiotic property is greater than the a sum of their individual prebiotic properties."

The state of the prior art: As set forth in 6,399,124 ('124), the fiber content of a single composition can provide up to a maximum of 10g of fiber (FOS, GOS, mixtures thereof) per dessert and that higher quantities in a dessert leave an unpleasant feeling of heaviness in the stomach (col. 5, ines 24-29; claims 102). The art teaches that a single composition should not contain more than 10 g of fiber and Applicant instant Examples do not contain more than 10 g of fiber (2 g. (Example 2), 9.86g (Example 3), and 2.5g. (Example 4)). With a broad general disclosure, Applicants have not provided a basis for how their invention would specifically work at the higher claimed limit of about 25g, about 20g or about 15g of fiber. It is clear from the prior art above that amounts in a single composition above 10g give discomfort to a person. Given the instant disclosure,

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one of ordinary skill in the art would have to resort to trial and error experimentation in order to practice the invention commensurate in scope with the claims.

The amount of direction provided by the inventor: There is nothing in the specification that would indicate that the current invention is capable of working at any amount higher than 10g (or the 9.86g of Example 3). Guidance for preparing a composition at the higher instant claimed values is not provided. As a result, one of ordinary skill in the art would have to revert to trial and error experimentation in order to practice the invention commensurate in scope with the instant claim set. With respect to the instant composition, there is a substantial gap between a composition comprising 2g, 2.5g, 9.86g and one comprising about 25g. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

The presence or absence of working examples: Guidance for preparing a compositions comprising 2g, 2.5g, and 9.86g of fiber in Examples in the instant specification is provided. There are no examples provided of any amount above 10g, and certainly not 25g, 20g or 15g and as such these amounts are not supported.

The quantity of experimentation: In the instant case, there is a substantial gap between a composition comprising 2g, 2.5g, and 9.86g (fiber) or about 25g, the specification is not supportive of the entire instant claimed range of about 25g, about 20g or 15g of fiber. Consequently, a burdensome amount of research would be

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required by one of ordinary skill in the art to bridge this gap. In order to utilize the invention as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. The instant disclosure is broad and generic. It is not clear what specific embodiments beyond 2g, 2.5g, and 9.86g of fiber would be required in order for one of ordinary skill in the art at the time the invention was made to practice the instant invention commensurate in scope with the claims.

The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then

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narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation of about 20g, and the claim also recites 15g which is the narrower statement of the range/limitation.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-8, 10-11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesens et al US 6,399,124 B1.

The instant claims are drawn to a composition comprising an oligosaccharide blend that comprises fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein (a) each a daily dosage of said oligosaccharide blend is about 25 g; (b) each of said oligofructose and oligogalactose are composed of chains with a degree of

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polymerization ranging from about 2 to about 7; (c) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (d) the FOS and GOS are capable of synergistically promoting the growth of Lactobacilli, such that their combined prebiotic property is greater than the a sum of their individual prebiotic properties.

- Lesens et al teaches composition comprising fermentable fibers specifically promoting the growth, in the intestinal tract, of the lactic acid bacteria contained initially in the ice cream for the treatment and/or prevention of gastrointestinal disorders, for strengthening the immune system, or for increasing the absorption of minerals (abstract) (according to the limitation of claim 1d and 27).
- Lesens et al teaches the composition contains prebiotic fibers (abstract), which may be of a protein or saccharide nature, chosen for example from vegetable pectins, chito-, fructo-, gentio-, galacto-, isomalto-, manno- or xylo oligosaccharides, etc (col. 4, lines 44-47; and claim 2) (according to the limitation of claim 1 and 27).
- The preferred galacto-oligosaccharides comprise a saccharide part consisting of 2 to 5 repeating units and preferred fructooligosaccharides are inulin-oligofructoses extracted from chicory which may comprise, for example, 1-9 repeating units (col. 4, lines 56-64; and claim 26). Examples 1, 4 and 5 specifically teach edible compositions, coatings and decorations containing galactooligosaccharide P7L, Raftilose L30 and Actilight 950P. (wherein these are the limitations of claim 1b and 27)

- The composition of Lesens et al teaches that the quantity of fibers in the dessert may contain from 0.1 to 20% of such fibers (by weight relative to dry matter content) (within the range as instant claimed in claim 1c and 27), and that a single dessert may be designed to provide up to a maximum of 10 g of fiber per dessert (col. 5, lines 15-25) (a generic teaching of the fiber in a single dessert, not a daily dose (which is a future intended use or means of administration) of claims 1 and 5 and therefore not given any patentable weight).
- Examples 4-5 of Lesens et al teach a cone made of Raftilose L30 (Table 7) or wafer dough of galactooligosaccharide P7L, respectively; and a decoration or coating such as that of Table 3 (galactooligosaccharide P7L) or Table 4 (Raftilose L30). Such a ratio would yield a weight ratio of 1.56 FOS:GOS in the single food composition (according to the limitation of 1c and 27).
- Example 4 teaches 1.1 g fibers are provided per ice cream cone, while Example 6 teaches 2.1 g of fiber from the sandwich. Claim 9 of Lesens et al teaches that about 0.1 to about 10% of the frozen dessert comprises fibers (wherein the limitations of claim 10 (i.e. 2.5g FOS/GOS fiber) are close to the disclosed ranges in the art).
- Lesens et al teaches compositions wherein the edible support alone comprises between about 1 to about 60% milk, between about 0.5 to about 5% of animal or vegetable proteins, between about 0.1 to about 10% fibers, between about 15% to about 30% sucrose and between about 2% to about 20% fat, by weight (claim 9) (wherein the limitations of claims 6-7 are met). Examples 1 and 2 teach that

a consumption of 200 mL or 100 g of ice cream per day provides proper dietary supplement (according to the limitation of claims 8). And it is the examiners position that all examples of Lesens et al are compositions that are ready-for-consumption and high in calories (meeting the limitation of claim 11).

- Lesens et al teaches compositions wherein the edible support alone comprises between about 1 to about 60% milk, between about 0.5 to about 5% of animal or vegetable proteins, between about 0.1 to about 10% fibers, between about 15% to about 30% sucrose and between about 2% to about 20% fat, by weight (claim 9). But examples 4-6 also teach compositions comprising flour, which provides a significant amount of carbohydrates (52g - 62g flour/100g total weight) (meeting the limitation of claim 10).

Lesens et al does not teach a composition of claim 10 or the specific dosage claimed in instant claims 1 and 5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Lesens et al to make a composition of FOS and GOS in a specific ratio, proteins, carbohydrates, and fats, and one of ordinary skill in the art would be motivated to experiment and optimize values to obtain workable ranges. As stated in MPEP 2144.05: "[W] here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

The skilled artisan would know how to optimize the amounts taught by Lesens et al to

obtain the optimal gastrointestinal benefit, since Lesens et al teaches a composition of fibers wherein the fibers are preferably FOS and GOS and teaches various examples comprising both and a single serving of up to 10g of fiber.

Claims 1, 5, 7-8, 10-11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al and Boehm et al and Rigo et al in view of Lesens et al US 6,399,124 B1.

Moro et al and Boehm et al and Rigo et al in view of Lesens et al teach the limitations of claims 1, 5, 7-8, and 10-11:

- Moro et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See pages 291, 294 and Table 1) (meeting the generic limitation of claims 1, 10 and 27). According to Moro et al., the oligosaccharide mixture can comprise between the 90% GOS and 10% FOS (page 292). This satisfies the weight ratio of FOS:GOS of about 0.5 to about 20 of claim 1c. According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation (according to the limitation of claim 27). As formulated, it is the examiner's position that the formula advanced by Moro et al. is both "nutritionally complete" and "ready-for-consumption"(according to the limitation of instant claim 11).
- Boehm et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and

protein (See page F179 and Table 1) (meeting the generic limitation of claims 1, 10 and 27). According to Boehm et al., the oligosaccharide mixture can comprise between the 90% GOS and 10% FOS (page F178) (according to the limitation of instant claim 1c). According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation (according to the limitation of claim 27). As formulated, it is the examiner's position that the formula advanced by Boehm et al. is both "nutritionally complete" and "ready-for- consumption" (according to the limitation of instant claim 11).

Moro et al and Boehm et al do not teach a composition comprising more than about 1 g of protein in 100 kcal of instant claim 7.

- Rigo et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See Table 1). According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation, and over 1% of protein can be present per 100 kcal (meeting the limitation of claim 7). As formulated, it is the examiner's position that the formula advanced by Rigo et al. is both "nutritionally complete" and "ready-for- consumption" (according to the limitation of instant claim 11).

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Moro et al, Boehm et al, and Rigo et al do not teach the exact percentages of ingredients and ratio of GOS to FOS as claimed.

- Lesens et al is taught above. Lesens teaches the ratio and percentages.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Moro et al and Boehm et al and Rigo et al in view of Lesens to make an composition comprising a mixture of prebiotic fibers such as FOS and GOS, and other ingredients for consumption. One of ordinary skill in the art would be motivated to experiment and optimize values to obtain workable ranges to treat those with gastrointestinal disorders, to promote the growth, in the intestinal tract, of the lactic acid bacteria, also for strengthening the immune system, or for increasing the absorption of minerals. As stated in MPEP 2144.05: *"[W] here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* Because the exact formulation and portion of a baby formula, nutritional supplement, or other edible composition is determined by age, size, health, and other variables it would be reasonable for one of ordinary skill in the art to experiment and optimize the values set forth in Moro et al and Boehm et al and Rigo et al in view of Lesens et al in order to obtain a composition capable of delivering the appropriate amount of nutrients to the patient.

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Claims 1 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesens et al US 6,399,124 B1 in view of Van Leeuwen et al US 2003/0138476 A1.

Lesens et al in view of Van Leeuwen et al teach the limitations of claims 1, and 26:

- Lesens et al is taught above and claims 1 and 27 are taught above. Lesens et al teaches composition comprising fermentable fibers specifically promoting the growth, in the intestinal tract, of the lactic acid bacteria contained initially in the ice cream for the treatment and/or prevention of gastrointestinal disorders, for strengthening the immune system, or for increasing the absorption of minerals (abstract).
- Lesens et al teaches the composition contains prebiotic fibers (abstract), which may be of a protein or saccharide nature, chosen for example from vegetable pectins, chito-, fructo-, gentio-, galacto-, isomalto-, manno- or xylo oligosaccharides, etc (col. 4, lines 44-47; and claim 2). Examples 1 and 2 teach that a consumption of 200 mL or 100 g of ice cream per day provides proper dietary supplement.

Lesens et al does not teach including glutamine (instant claim 26), but does teach compositions containing milk, animal or vegetable proteins, which are known to contain glutamine (claim 9).

- Van Leeuwen et al teach nutritional preparations such as baby food or enteral food (abstract) which include prebiotics such as fructo-oligosaccharides and

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galacto-oligosaccharides and further glutamine or an equivalent such as is known in the art (pg. 1, [0013-0014], pg. 2, [0017]). Further, Van Leeuwen et al claims a nutritional preparation as a nutritional preparation with also contains glutamine or equivalent thereof and further prebiotics such as galacto-oligosaccharides and fructo-oligosaccharides (claims 1-3, 8, and 12) (meeting the limitation of instant claim 26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the compositions as taught by Lesens et al with glutamine as taught by Van Leeuwen et al. One of ordinary skill in the art would have been motivated to combine the teachings since both teach nutritional compositions that help the intestinal tract and provide fibers such as prebiotics (galacto-oligosaccharides and fructo-oligosaccharides). As such one would have a reasonable expectation of success in adding the glutamine of Van Leeuwen et al to the compositions of Lesens et al, especially since Van Leeuwen et al teaches that products which are rich in glutamine include vegetable proteins (pg. 1, [0005]), as is already taught by Lesens et al (claim 9).

Response to Arguments

Applicant's arguments with respect to claims 1, 5-8, 10-11 and 26-27 have been considered but not persuasive and are moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicants argue that Lesens et al does not teach compositions to be used with a daily dosage of "about 25g" of fiber of FOS and

GOS mixture. The Examiner respectfully disagrees, as Lesens et al teach both galactooligosaccharides and fructooligosaccharides are preferred and claims "mixtures thereof" (col. 4, lines 56-64; and claim 26), in an amount up to 10g; Applicant's instant specification does not teach how to make a use a formulation above 10g of fiber and further administration of a daily dosage could comprise more than one, single unit of the instant claimed composition, which is therefore future intended use and as such is given no patentable weight. The instant specification [0083] teaches that daily a patient can take a composition up to 5-6 times, while the instant claims are directed to what is comprised within a single composition, not in a daily dosage. Instant claim 10 in fact teaches that the composition has 2.5g total FOS and GOS, which is taught by the art as detailed above. In fact the prior art teaches that including more than 10g of fiber in a single dessert serving causes gastrointestinal discomfort and Applicant has not shown that the higher amount does not cause discomfort. Further, the addition of new claim 27 with the language 'consisting essentially of' does not overcome the prior art of record and is treated as 'comprising' since Applicant does not provide evidence that additional components would materially change the characteristics of the instant invention. As the MPEP 2163 states: "For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as

constituting a material change in the basic and novel characteristics of the invention."). See also *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239-1240, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003); *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also MPEP § 2111.03. The claim as a whole, including all limitations found in the preamble (see *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention)), the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, *Lesens et al* teaches in examples 1, 4 and 5 ice cream put into a cone or wafers containing either (galacto-oligosaccharides or fructo-oligosaccharides) that is coated with composition of Table 2 (containing galacto-oligosaccharides) or Table 3 (containing galacto-oligosaccharides) and decorated with a topping of Table 4 containing fructooligosaccharides. *Lesens et al* further claims fibers of between about 0.1 to about 10% including fibers like galacto-oligosaccharides and fructo-oligosaccharides (claims 1-2, and 9) and as such that these fibers are useful for

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promoting the growth of the lactic acid bacteria in a human intestinal tract. Lesens et al renders obvious the instant claims 1, 3, 5-8, 10-11 and 27.

Applicant also argues that the prior art does not teach synergistic effect of FOS and GOS, however Lesens et al does teach that the edible composition containing the fibers (FOS and GOS) promote the growth of the lactic acid bacteria in a human intestinal tract (abstract, claim 1) and as such proves that these fibers enhance lactic acid bacteria growth. The property or function of promoting lactic acid bacteria by ingestion of FOS and GOS are not separable from the structure of FOS and GOS as taught by Lesens et al. Simply because Lesens is silent to the synergism of FOS and GOS does not take away from the fact that the art teaches FOS, GOS are preferred and mixtures thereof, since the prior art teaches a composition and process for forming said composition described by applicants instant application, but applicants observation that it also has 'synergistic effect' does not give it patentable weight, since it is the same composition and same process of making, as adding a characterization to a prior art patented invention is not patentable. Applicant further points to Lesens et al (col. 5, lines 23-36) as a teaching away, the Examiner respectfully disagrees. This section teaches that (as does claim 9) that a substantial amount of fiber (which is preferably FOS and GOS) is added to the composition, but that not more than 10 g. is added per dessert (or a total 0.1-20% by weight of fiber). The amount of fiber claimed in Lesens et al (claim 9) is not outside the scope of the instant claim 10 which claims only 2.5% fiber; therefore there is no teaching away only an 'upper limit' placed on the fiber amount.

Also, Boehm et al teaches that the combination of FOS and GOS promotes beneficial intestinal bacteria in a synergistic way so that lactobacilli can grow (pg. F178, last paragraph and Abstract "conclusion"). Moro et al teaches that the optimal dosage of the FOS and GOS mixture are is 0.8 g/dL which produces a more pronounced bifidogenic effect than 0.4 g/dL, which indicates a synergistic effect of FOS and GOS (pg. 294, last paragraph-pg. 295 end); while Moro et al teaches that there was no difference in the dosages (0.4 or 0.8 g/dL) for the Lactobacilli, but that the number of Lactobacilli was significantly higher (at day 2 of the 28 day study) for both supplemental groups than the placebo group (pg. 293, last paragraph-pg. 294, lines 1-2). Rigo et al teaches that the use of prebiotics ("material and methods" uses a mix of FOS and GOS) resulted in a rapid and significant increase in the percentage of endogenous bifidobacteria and the ability to maintain a stable intestinal flora (pg. 39, summary "conclusion"). As such it is the examiners opinion that the art supports the synergistic effect of FOS and GOS in the growth of intestinal bacteria such as Lactobacilli.

Applicant's argue that there is no prima facie case of obviousness and no motivation to combine Lesens et al and Van Leeuwen et al, and the examiner respectfully points out that applicant's argue against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It should be noted that the motivation to combine references can be different from the ones set forth by Applicant. That is, as long as motivation exists to combine the elements, the problem to be solved does not have to involve the same reason. As such, the examiner respectfully submits that there is motivation to combine the teachings of Lesens et al and Van Leeuwen et al and the expected result of a fiber containing composition of prebiotics (FOS and GOS) and glutamine that produces beneficial gastrointestinal results. Lesens et al teaches GOS and FOS are preferred and mixtures thereof for intestinal tract health and further Example 7 of Van Leeuwen teaches a composition of FOS and lactose while Example 3 of Van Leeuwen teaches that GOS is substituted for lactose and, as such the art seems to point to the fact that GOS can be substituted for lactose. Lesens et al teaches generically proteins and fibers (mixtures of GOS and FOS) for intestinal health, while Van Leeuwen also specifically adding glutamine and prebiotics (such as GOS and FOS) benefits the intestinal wall. Thus motivation to combine the prior art exists as both are directed to improving intestinal health with prebiotics (FOS and GOS) and proteins (Van Leeuwen teaches glutamine).

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BETHANY BARHAM whose telephone number is (571)272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Examiner 1615

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